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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,741	11/30/2001	Mary M. Dyszlewski	1328 WO/US	2094

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11/21/2003

Jeffrey S Boone
Mallinckrodt Inc
675 McDonnell Boulevard
PO Box 5840
St Louis, MO 63134

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/21/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,741

Applicant(s)

DYSZLEWSKI ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 10-16, 23-26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 10-16, 23-26, 28, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1616

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 5, filed 8/21/03, wherein the specification was amended; claims 1-5, 8, 9, 17-22, and 27 were canceled; and claim 29 was added.

Note: Claims 6, 7, 10-16, 23-26, 28, and 29 were amended.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 8/21/03 (Paper No. 5) to the rejection of claims 1-28 made by the Examiner under 35 USC 102, 103, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Double Patenting

The double patenting rejection is WITHDRAWN for reasons of record in Applicant's response.

102 Rejections

I. The rejection of claims 6, 7, 10-16, and newly added 29 under 35 USC 102(a) as being anticipated by Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7987-7988) is MAINTAINED for reasons of record in the office action mailed 2/5/03, Paper No. 3, and those set forth below.

Applicant asserts that while the reference discloses the ligands picolinamine-N,N-diacetic acid (PADA) and aminopolycarboxylic acid, as well as imino-N,N-diacetic acid, the PADA contains an aromatic pyridine which is believed to be the relevant portion of the molecule useful in forming a stable Tc(I)-tricarbonyl complex.

Art Unit: 1616

Furthermore, Applicant asserts that the imino-N,N-diacetic acid portion of the molecule will not stabilize Tc(I) very well.

Applicant is reminded that the claim is directed to generating a complex of formula II. Alberto et al generated the complex using the components disclosed in Applicant's claims. Whether the complex is stable indefinitely or for a specified period of time is not the issue. Stability is a relative term. While Applicant states that the imino-N,N-diacetic acid portion will not stabilize Tc(I), it is unknown how long Alberto et al complex is stable. In other words, Applicant has not provided data to illustrate why the same complex in the art is not stable as Applicant's complex generated with the same components as set forth in the instant invention. Furthermore, it should be noted that although Tc(I) is considered to be 'soft' and ligands like PADA (aminopolycarboxylic acid) are rather expected to form stable complexes with harder metal centers, the complex ([Tc(PADA)(CO)₃]) exhibited high stability and endured refluxing for hours.

II. The 102 rejection over Alberto et al (WO 98/48848) is WITHDRAWN because Applicant has amended the claims to overcome the rejection.

103 Rejections

I. The rejection of claims 6, 23, 24, 26, 28, and 29 under 35 USC 103(a) as being unpatentable over Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7887-7988) is MAINTAINED for reasons of record in the office action mailed 2/5/03, Paper No. 3 and for those set forth above under the 102 rejection section.

II. The 103 rejection over Alberto et al (WO 98/48848) is WITHDRAWN in view of the new grounds of rejection below.

Specification

It is duly noted that Applicant has made the appropriate changes to the specification.

NEW GROUNDS OF REJECTION

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6, 7, 10-16, 23, 24, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberto et al (WO 98/48848) in view of Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7987-7988).

Alberto et al disclose a method of preparing facial metal tricarbonyl compounds using them to label biologically active substrates. The compounds have the formula of $[M(OH)_2(CO)_3]$ and are generated by reacting a metal in the permetallate form with carbon monoxide and a reducing agent. In addition, a stabilizing agent may be present. Various substrates such as amino acids, peptides, proteins, sugars, small receptor binding molecules and body cells may be labeled. Also, Alberto et al disclose a kit for the preparation of the labeled complex (see entire document, especially, abstract; page 2, lines 20-31; page 3, lines 20-28; page 4, lines 1-35; page 5, lines 4-35; page 6, lines

Art Unit: 1616

16-35; and page 7, lines 16-25). However, Alberto et al (WO 98/48848) fail to disclose that Lx in Formula II may be aminopolycarboxylate.

Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7987-7988) disclose the synthesis of $Tc(OH)_2(CO)_3$ and the labeling of biomolecules. In addition, Alberto et al disclose that the ligands PADA (aminopolycarboxylic acid) may be used with their invention.

~~It would have been obvious to one of ordinary skill in the art at the time the~~ invention was made to modify the invention of Alberto et al (WO 98/49948, REF #1) using the teachings of Alberto et al (J. Am. Chem. Soc., 1998, 120, pp. 7987-7988, REF #2) and use aminopolycarboxylate multidentate ligands because REF 1 disclose Applicant's Formula II and discloses that in the formula $fac-[M(CO)_3L_3]_n$, L3 may be a monodentate ligand. REF #2 discloses while Tc(I) is considered to be 'soft' and ligands like PADA are expected to form stable complexes with harder et al centers, the Tc-PADA-(CO)₃ exhibited high stability for hours (page 7988, column 1, second complete paragraph). Since both references are directed to compounds encompassed by the formula $fac-[M(CO)_3L_3]_n$, the references may be considered to be within the same field of endeavor. Hence, the references are combinable.

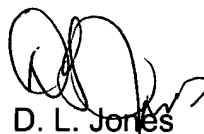
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. ~~In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.~~

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
Art Unit 1616

November 20, 2003